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SUBJECT: UNITED STATES AND GERMANY IN GENERAL AGREEMENT ON OVERSIGHT OF THE DNA SYNTHESIS INDUSTRY

REF: A. 08STATE 127980
¶B. STATE 4627

¶1. Summary: The German government is approaching oversight of the DNA synthesis industry by relying on the Industry Association for Synthetic Biology (IASB) to develop and promote voluntary self-regulation. The proposed IASB oversight mechanisms are very much in line with the USG policy framework on this issue. While Germany has not specifically regulated the DNA synthesis industry, existing German genetic engineering regulations effectively require many of the screening and record keeping components of the proposed USG framework and IASB recommendations. Germany also has regulations that provide additional oversight mechanisms not present in the United States, especially in the area of personnel reliability. The U.S., Germany, and IASB also have similar views on the scientific and software challenges that need to be resolved for effective technical screening. Law enforcement in Germany, however, is largely implemented by the Laender (states), providing challenges for international law enforcement cooperation.

¶2. The United States and Germany agreed to meet again in person in three or four months, and possibly earlier via teleconference. Future meetings will be to share future USG developments on technical and customer screening, record keeping, and communication between law enforcement and DNA synthesis providers. The United States and Germany agreed to work together to promote a screening framework in the international community, utilizing various multilateral fora, as a screening will only be effective if harmonized internationally. End Summary.

¶3. Based on recommendations from the National Science Advisory Board for Biosecurity (NSABB), the USG is currently developing a framework for screening of commercial orders for gene synthesis. The United States and Germany are the two most active countries in this new and fast growing field of DNA synthesis, but many other countries are involved. As the USG begins to work out the parameters of these guidelines, it seeks to coordinate efforts with other important players to ensure consistent international practices.

¶4. The USG requested a meeting with the German government (Ref. A) to bring together representatives of the relevant federal agencies in both countries to share current policy views and practices in this area. The proposed agenda is contained in Ref. B.

¶5. The first round of discussion took place on Feb. 23, 2009, in Berlin. Six USG representatives from the Departments of State (ISN/CB), Commerce (BIS), Homeland Security (S&T), Health and Human Services (ASPR), and Justice (FBI) attended. German attendees included representatives from counterpart agencies in the German government as well as the Ministry of

Education and Research, and representatives of the Industry Association for Synthetic Biology (IASB; soon to be renamed the International Association for Synthetic Biology), the major industry consortium of DNA synthesis providers.

¶6. The USG representatives provided presentations on an overview of USG activities with respect to dual-use life science research, a summary of the USG policy framework for addressing government oversight of DNA synthesis orders, and a review of the dialogue between the FBI and major DNA synthesis providers. German representatives presented existing German and EU laws and regulations that provide mechanisms that effectively provide oversight of dual-use biological research. IASB representatives presented an industry perspective on DNA screening of synthesis providers. Discussion focused on understanding the legal and regulatory frameworks in each country and identifying commonalities in approaches and issues for future collaboration.

¶7. Risk and Technological Change: The Germans do not see a high-level or near-term risk, but agree that DNA synthesis requires oversight. In response to the suggestion by one industry representative that consideration be given to registering high throughput DNA synthesizers, there was some inconclusive discussion about whether or not monitoring synthesizers was useful. Both sides agreed that regulatory frameworks need to be adaptive in light of the rapid rate of increase in DNA synthesis capability by both gene foundries and desktop synthesizers.

¶8. Extant German Legal Frameworks: Germany has several regulatory mechanisms that implicitly provide oversight of the DNA synthesis industry. The relevant regulations include genetic engineering regulations, codes of conduct affecting grant proposal preparation and review, personnel reliability practices for working in BSL-3/4 laboratories, and licensing of life scientists working with specific pathogens. Current German research funding practices, however, do not allow funding to be tied to a requirement to buy only from companies that screen orders.

¶9. Law Enforcement: Germany is very interested in U.S. efforts to provide guidance to industry on reporting suspicious orders and would like followup information as policies evolve. Personnel reliability is enforced through multiple mechanisms: life scientists are licensed for working with specific pathogens and BSL-3/4 workers require security clearances. Items checked include criminal history, financial history, mental health status, and personal interviews. Germany has challenges in providing a single point of contact for suspicious orders because of the dominant role of the Laender in law enforcement. Germany does not appear to have considered how to handle company concerns regarding suspicious orders. Also, there currently does not appear to be a mechanism to allow the United States to alert Germany about suspicious orders.

¶10. Technical Challenges to Be Resolved: The German government, German industry representatives, and the USG have common views on the technical challenges for implementing a screening framework, particularly on an international basis. These issues include database content and annotation of sequences for both pathogenicity and housekeeping, access control for both modifying and using content, and whether or not a database should be centralized or distributed. Responsible parties for maintenance and curation need to be designated.

¶11. Strategy for International Engagement: The United States and Germany agree that broad international adoption requires early engagement of key developing countries in addition to key developed countries. Promoting global adoption of screening will also require engaging multiple multilateral fora including OECD, WHO, BWC, Australia Group, and other nonproliferation venues. The IASB can also play a pivotal role in reaching out to gene foundries in developing countries. It is critical that the developing countries not perceive this effort as being pushed on them by the developed

countries, but buy into it as industry "best-practice."

¶12. Future Discussions: German government and industry representatives readily agreed to the US suggestion to hold another face-to-face meeting once US studies of technical aspects of order screenings were better-developed. US also suggested that a video conference in April might be useful. US and German representatives agreed to jointly brief other close allies at a planned meeting in Paris on March 4, 2009.

¶13. Comment: IASB representatives were much more engaged in the discussions than those from the German government (apart from Foreign Ministry technical expert Volker Beck). Clearly, the German government is generally content to let industry take the lead. While Germany will be supportive, they are not inclined to be particularly energetic in seeking adoption by other governments. The industry association, on the other hand, may be a very active partner. In future bilateral discussions, participation of German industry should be continued. End Comment.

¶14. Members of the U.S. delegation have cleared on this cable.
Koenig